OBJECTIVES: The aim of the study was to assess the prevalence and risk factors for diabetes mellitus among patients of North India.

METHODS: It is a prospective observational study conducted at endocrinology clinic of a public tertiary care hospital in north India. Patients of either gender with greater than 18 years of age and having the diagnosis of T2DM were recruited in the study. Each and every patient had undergone a random blood sugar test and fasting plasma glucose was recorded in each patient. Data was taken from patient’s medical records. Binary logistic regression was done to assess the risk factors. RESULTS: A total of 2,006 T2DM subjects were recruited in the study and each and every patient had undergone a random blood sugar test and fasting plasma glucose was recorded in each patient. Data was taken from patient’s medical records. Binary logistic regression was done to assess the risk factors.

CONCLUSIONS: This study showed higher prevalence of DR in Indian population thus suggesting a need of regular eye examination.

PDB21

STATUS OF RETINOPATHY IN TYPE 2 DIABETES MELLITUS PATIENTS OF NORTH INDIAN POPULATION

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OBJECTIVES: To determine whether there was an association between insulin dose and all-cause mortality and other serious events in people with type 2 diabetes treated with insulin plus metformin, and to determine if concomitant metformin with insulin reduced the risk of adverse outcome versus insulin monotherapy.

METHODS: For this retrospective cohort study, subjects with type 2 diabetes who progressed to treatment with insulin monotherapy or insulin plus metformin from 2000 onwards were identified from the UK Clinical Practice Research Datalink (CPRD). The risk of all-cause mortality and a combined endpoint of any incident major cardiovascular event (MACE), cancer, or death was compared using the Cox proportional hazards model. Weight-standardised daily prescribed insulin dose (iu/kg/day) was modelled as a time-dependent, continuous co-variate. RESULTS: 11,340 subjects were identified. There were 1,840 deaths and 1,751 combined events (excluding those with a history of large vessel disease or cancer). The corresponding event rates were 43.7 deaths and 62.3 combined events per 1,000 person-years. For all-cause mortality, the adjusted hazard ratio (aHR) for insulin dose (relating to an increase of 1 iu/kg/day) was 1.81 (95% CI 1.66 to 1.98) in the combined insulin group (insulin plus metformin) and 1.39 (95% CI 1.10 to 1.76) in the insulin plus metformin group. For people in the combined insulin group (insulin + metformin), the aHR for concomitant metformin was 0.68 (95% CI 0.42 to 0.54). These patterns were confirmed for the combined endpoint. CONCLUSIONS: There was a dose-response association between insulin dose and all-cause mortality in people treated with insulin plus concomitant metformin. Concomitant metformin was associated with a halving of the risk of death in people with type 2 diabetes injecting insulin.

PDB19

FRAMINGHAM RISK SCORE ESTIMATES HIGHER CVD RISK THAN UKPDS RISK ENGINE IN NEWLY DIAGNOSED TYPE 2 DIABETES MELLITUS PATIENTS IN NORTH INDIA

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OBJECTIVES: To assess ten year cardiovascular disease (CVD) risk in newly diagnosed type 2 diabetes mellitus (duration of diagnosis ≤ 6 months) patients using Framingham risk score (FRS) and UK Prospective Diabetes Study (UKPDS) Risk Engine in a public tertiary care hospital in north India and to assess the agreement between both the risk scores. METHODS: This is a prospective, observational, questionnaire based study. Patients aged 18-70 years of both sexes were included in the study. All data were collected by oral interview and clinical records of patients after obtaining informed consent from patients. Ten year CVD risk was calculated for 324 patients using FRS and UKPDS Risk Engine. FRS uses participant age, sex, total cholesterol, high-density lipoprotein cholesterol, smoking status, blood pressure and presence or absence of diabetes. UKPDS Risk Engine, a diabetes specific algorithm, uses HbA1c and ethnicity of the patient in addition, for assessing ten year CVD risk. RESULTS: Out of 324 patients, 217 (67.1%) were females [n = 180 (55.6%)] and 107 (32.9%) were males. The Framingham risk score estimated CVD risk was 11.1% in males and 11.3% in females [9.8% (10.4%)]. Inter-rater agreement assessed using weighted Kappa statistic showed a poor agreement between both scoring systems with a k value of 0.18 (95% CI 0.12-0.23). CONCLUSIONS: Framingham risk score overestimated the ten year CVD risk compared to UKPDS Risk Engine. As till date, CVD risk score development in the Indian population was limited. This study presents a valuable contribution regarding Indian type 2 diabetes patients.

PDB20

THE IMPACT OF CONCOMITANT METFORMIN ON MORTALITY AND OTHER SERIOUS OUTCOMES IN PEOPLE WITH TYPE 2 DIABETES TREATED WITH INSULIN MONOTHERAPY

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OBJECTIVES: To determine whether there was an association between insulin dose and all-cause mortality and other serious events in people with type 2 diabetes treated with insulin plus metformin, and to determine if concomitant metformin with insulin reduced the risk of adverse outcome versus insulin monotherapy.

METHODS: For this retrospective cohort study, subjects with type 2 diabetes who progressed to treatment with insulin monotherapy or insulin plus metformin from 2000 onwards were identified from the UK Clinical Practice Research Datalink (CPRD). The risk of all-cause mortality and a combined endpoint of any incident major cardiovascular event (MACE), cancer, or death was compared using the Cox proportional hazards model. Weight-standardised daily prescribed insulin dose (iu/kg/day) was modelled as a time-dependent, continuous co-variate. RESULTS: 11,340 subjects were identified. There were 1,840 deaths and 1,751 combined events (excluding those with a history of large vessel disease or cancer). The corresponding event rates were 43.7 deaths and 62.3 combined events per 1,000 person-years. For all-cause mortality, the adjusted hazard ratio (aHR) for insulin dose (relating to an increase of 1 iu/kg/day) was 1.81 (95% CI 1.66 to 1.98) in the combined insulin group (insulin plus metformin) and 1.39 (95% CI 1.10 to 1.76) in the insulin plus metformin group. For people in the combined insulin group (insulin + metformin), the aHR for concomitant metformin was 0.68 (95% CI 0.42 to 0.54). These patterns were confirmed for the combined endpoint. CONCLUSIONS: There was a dose-response association between insulin dose and all-cause mortality in people treated with insulin plus concomitant metformin. Concomitant metformin was associated with a halving of the risk of death in people with type 2 diabetes injecting insulin.

PDB22

REGIONAL ESTIMATES OF THE PREVALENCE OF DIABETES MELLITUS IN GERMANY FOR 2011 AND 2022 BASED ON PRESCRIPTION DATA

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OBJECTIVES: In Germany, regional data on diabetes prevalence are scarce. Robust regional prevalence estimates are required for allocating limited health care resources appropriately. The aim of this study was to determine the regional diabetes prevalence in Germany for 2011 and 2022.

METHODS: A large database containing 60 prescriptions and claims redeemed in German pharmacies supported by the statutory health insurance (SHI) was analyzed. By defining a prescription filter for anti-diabetic agents, the numbers of drug treated diabetic patients in different sex groups were estimated for all 16 federal states in Germany. A multiple linear regression model was used to adjust the values to the whole SHI population with the help of an additional database containing exhaustive drug sales data. Quick analyses and demographic forecasts can support care providers and payers to plan health care and expenses more efficiently to match current and future regional demand.

PDB23

CHANGES IN PATIENT CHARACTERISTICS AND TREATMENT PATTERNS AMONG PATIENTS WITH TYPE 2 DIABETES IN THE UNITED STATES FROM 2006-2013

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OBJECTIVES: Type 2 diabetes can be a particular health concern, affecting an estimated 371 million of the world’s population. The objective of this analysis is to review epidemiologic and treatment pattern trends among US adults with T2D from 2006 to 2013. METHODS: This analysis was derived from an extensive database: National Health and Wellness Survey (NHWS) from 2006 (n=62,834) through 2013 (n=75,000). A stratified random sampling based on gender, age, and race/ethnicity was used to ensure representativeness to the adult population, based on the US Census Bureau. Descriptive analyses were conducted by each year to determine changes in the overall T2D population with respect to demographics, HbA1c levels, complications, treatment, and time-to-insulin or oral/non-insulin injectable medications. RESULTS: The overall prevalence of T2D fluctuated slightly from 2006 to 2013, ranging from 9.2% to 10.2% over time. While the mean age at diagnosis for T2D patients has been consistently in the late forties, from 2006 to 2013 the mean age at diagnosis has decreased by 1.5 years overall (49.9 to 48.4 years). Though the majority of patients are non-Hispanic White, there has been a slow increase in the proportion of patients who are African-American or Hispanic (24.5% in 2006 vs 26.6% in 2013). The proportion of patients who are using an oral medication, insulin, or non-insulin injectable has steadily increased (80.4% in 2006 to 82.5% in 2013). Mean years from diagnosis to using insulin has steadily increased, as well as usage of newer classes of medications such as GLP-1 (1.9% in 2006 to 4.2% in 2013). Knowledge of HbA1c has increased steadily from 2006 to 2013. CONCLUSIONS: While some trends of US adult T2D patients have remained steady, since 2006 there has been slower diagnosis, more Non-White patients, increases in treatment, and greater HbA1c awareness.

PDB24

PREVALENCE AND ECONOMIC BURDEN OF DIABETES IN AFRICA

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OBJECTIVES: Rising rates of diabetes in Africa have triggered increased demand for affordable medical solutions. This analysis sought to quantify the burden of diabetes in Africa, and identify regions where disease burden creates opportunity for pharmaceutical and medical device intervention. METHODS: The agenda of the International Diabetes Federation was used to estimate the prevalence of diabetes mellitus and the mean national expenditure in 53 African countries. A systematic literature search was conducted to gather current disease management protocols and practice in Africa. RESULTS: In 2013, there were an estimated 33.2 million
adult (ages 20-79) diabetes patients in Africa, -1.5 times the prevalence in 2003. The continuous Explore 10% increase in diabetes in 2013 was -$17.06 billion, compared to $2.72 billion in 2010, accounting for -15% of global expenditures despite a prevalence burden of nearly 10% of total figures. The highest proportion of diabetes cases and spending were from northern Africa (40.4% of cases, 41.8% expenditures in 2013). However, there was inter-country variability of prediabetes and diabetes, i.e. considering Africa (9.3% cases, 10.9% expenditures), and central Africa (8.6% cases, 4.2% expenditures), should higher burdens of disease than their share of expenditures. In contrast, southern Africa (8.9% cases, 36% expenditures) has a long pedigree of overall patient study period, but spends significantly more than other regions. Data indicate that access to diabetes treatment is highly variable by region, and that disease management programs are infrequently available. Drug therapies are more broadly available, though costs can be a significant barrier to utilization. Conclusions: Reductions in diabetes prevalence will continue to stimulate demand for medical solutions in Africa. Northern and southern Africa present a noteworthy market opportunity due to high disease prevalence and potentially high economic impact from diabetes spending per person in countries such as for the variability in local market economics and implementation infrastructure are needed to support the growing diabetes burden in Africa.

PDB25
EXAMINING DIABETES PREVALENCE IN THE UNITED STATES USING A 2008-2009 MEDICAID POPULATION

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OBJECTIVES: The aim of this study was to examine the geographic, age, gender and race variations in the prevalence of diabetes in the U.S. Medicaid population.

METHODS: This retrospective study analyzed a patient sample from the Medicaid fee-for-service (FFS) population in 2008 and 2009. Patients diagnosed with diabetes using International Classification of Disease, Clinical Modification (ICD-9-CM) diagnosis codes 250.20 and 250.2x. Continuous Medicaid FFS enrollment was required during the 2-year study period. Patients were required to have managed care enrollment in any month during the study period. Diabetes prevalence was analyzed by region, state, age, gender and race. The number and percentages of patients in each category were provided in the descriptive analysis. RESULTS: A total of 421,596 patients (16.66%) were diagnosed with diabetes in the Medicaid FFS population. Patients over age 60 years had a higher prevalence (23.00%) than those age 40-59 (19.53%) or 0-39 years (3.27%). Prevalence was also examined by race, with the highest prevalence found in Asian patients (22.17%), followed by Black (20.42%), Hispanic (16.94%), White (15.91%) and Native American (8.89%) patients. Prevalence of diabetes was much higher for female (18.36%) than for male patients (13.99%). U.S. states with the highest prevalence were Maryland (27.42%), Connecticut (26.73%), North Carolina (25.72%), and New Mexico (25.35%). Insulin use was also stratified by U.S. region: Midwest (18.12%), South (17.11%), Northeast (16.59%) and West (7.60%). CONCLUSIONS: The study results illustrate that elderly patients had a higher probability of being diagnosed with diabetes. Asian patients were more likely to be diagnosed with diabetes compared to other races. Female patients were at a higher risk for diabetes. Patients who resided in the Midwest U.S. region also had an increased likelihood of a diabetes diagnosis.

PDB26
THE OPTIMAL INTERVAL OF DIABETES MELLITUS SCREENING IN HEALTHY ADULTS: A RANKED EFFECTS MODEL

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OBJECTIVES: Diabetes mellitus (DM) screening using hemoglobin A1c (HbA1c) is important at identifying patients at risk of cardiovascular disease. Little information is available on strategies for monitoring including frequency and timing of re-screening. We aimed to estimate the long-term between-person variation (“signal”) and short-term within-person variation (“noise”) of the HbA1c measures and evaluated the optimal interval of re-checking HbA1c levels for DM screening. METHODS: We conducted a retrospective cohort study including enrolled all people who consecutively visited the St. Luke’s International Hospital Centre for Preventive Medicine (Tokyo, Japan) for a health check-up between 2005 and 2010. We measured the serum HbA1c annually. We estimated the ratio of “signal” to “noise” for HbA1c, adjusting for age, gender, using the random effects model. When the ratio of signal to noise was >1, we considered that screening interval appropriate. RESULTS: A total of 34,662 apparently healthy Japanese adults not taking diabetes medication at baseline had annual check-ups over 5 years. The mean age of the participants was 49 years old (SD: 12, range: 21 to 95) and 52% were male. Mean core body temperature (AUC0-1) statistic. We validated resulting prediction models in an independent data-set. Our baseline model accurately predicted progression to T2D from normoglycemia (AUC = 0.76). We validated this model with an independent data-set where the AUC increased to 0.78. When the model was extended to include time-dependent covariates the AUC increased to 0.87. Our model of progression from normoglycemia to T2D consisted of established risk factors (blood glucose measures, hypertension, income, race, triglycerides, lipid disorders, and blood pressure), whereas predictors of progression to prediabetes (moat variables) and T2DM were age, smoking, BMI, body temperature (AUC0-1, PRD10>1, PDB28
BUDGET IMPACT ANALYSIS OF VILDAGLIPTIN AS ADDITION TO ANALOGUE INSULINS IN TYPE 2 DIABETES MELLITUS TREATMENT IN COLOMBIA

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OBJECTIVES: Estimating the budget impact of the introduction of vildagliptin as addition to insulin in the treatment of patients with type 2 diabetes with inadequate glycosylated control (HbA1c >7%) compared to the same group of patients treated with the addition of insulin in Colombia, from a third-party payer perspective.

METHODS: Markov model, which simulates the natural history of the disease, budget impact analysis (AlP) was made under the Colombian context for a five-year period using direct health costs associated with the natural history of the disease, including macrovascular and microvascular events and episode of hypoglycemia in a mobile cohort of patients, looking at prevalence, incidence and death. In the alternative scenarios, we will estimate reductions in insulin doses for the corresponding arm vildagliptin in addition to insulin. Direct health care costs were taken from insurers and individual records of health benefits (RIPS) 2012. RESULTS: With a disease prevalence and incidence rate of 0.4% and 0.0087% respectively in Colombia and assuming that 8.6% of patients require insulin according to the stage of the disease, the cumulative cost to 5 years of patients treated with insulin alone, would be COP $3,030,742,552,215(USD1.565.522,80), compared to COP $3,546,840,289,383(USD 1.832.111,85) treated with insulin + Vildagliptin. Additionally, contemplating a reduction of approximately 27% in the dose of insulin, savings were generated under the use of vildagliptin in addition to insulin from the third year on total cost as well as reduction of cardiovascular and adverse events. Similarly, savings accumulated over the 5 years were equal to $0.0006 (0.09%) in 5 years, accompanied by lower mortality. CONCLUSIONS: The use of vildagliptin in addition to insulin will be significantly less expensive than using insulin monotherapy for patients with type 2 diabetes with inadequate glycosylated control, in the Colombian health system context, along with better health care outcomes.

PDB29
BUDGET IMPACT OF PHENTREMINE AND TOPRIMATE EXTENDED-RELEASE (PHENT/PREM ER) IN OVERWEIGHT AND OBESE PATIENTS WITH COMORBID PREDIABETES OR TYPE 2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: This post-hoc analysis estimated the budget impact of PHENT/PREM ER 7.5/46 mg in comparison with lifestyle modification (LM) alone in overweight and obese patients with comorbid prediabetes or T2DM. METHODS: A 1-year budget impact model was developed from the health plan perspective evaluating pharmacy costs and comorbidity costs in overweight and obese patients with prediabetes or T2DM. Changes in body mass index (BMI) for PHENT/PREM ER 7.5/46 and LM were based on data from CONQUER, a phase 3, 56-week randomized trial (Gadde 2011). Comorbidity cost offsets for BMI reductions were calculated by multiplying the change in BMI by medical ($164) and pharmacy ($113) costs per unit of BMI (Wang 2006). The rate of progression from prediabetes to T2DM was based on data from CONQUER. Literature-based estimates of the annual cost of treating prediabetes ($355) and T2DM ($8069) were used to calculate comorbidity costs. The plan population was expanded to include 1,800 patients and the market penetration of PHENT/PREM ER 7.5/46 was assumed to be 1% at a weighted cost per capsule of $5.04. RESULTS: In patients with prediabetes, BMI was reduced by 4.06 kg/m^2 for PHENT/PREM ER 7.5/46 and 2.7 kg/m^2 for LM, translating to cost offsets of $191 for PHENT/PREM ER and $125 for LM, respectively. The rate of progression from prediabetes to T2DM was 3.8% for PHENT/PREM ER and 9.6% for LM. In patients with T2DM, the BMI reduction was 3.69 kg/m^2 for PHENT/PREM ER 7.5/46 and 1.96 kg/m^2 for LM, translating to cost offsets of $1022 and $543, respectively. The budget impact of adding PHENT/PREM ER 7.5/46 mg in comparison with lifestyle modification (LM) alone in overweight and obese patients with comorbid prediabetes or T2DM is minimal and is offset by reduced comorbidity costs.